

REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 112, are respectfully requested.

Status

As is correctly reflected in the Office Action Summary, Claims 40-83 are pending. Claims 40-42, 44, 48, 50, 51, 54-63, and 75 are allowed. Remaining Claims 43, 45-47, 49, 52-53, 64-74, and 76-83 stand rejected.

Summary of Amendments

By the foregoing amendments, Claims 45, 46, and 64-73 have been amended to specify detection of any "antigen/antibody type reaction product formed." Support for these amendments may be found at least at Page 6, Lines 11-18, of the Specification, as noted by the Examiner. See *Official Action mailed November 25, 2003, Page 3*. Accordingly, no new matter has been added.

Also by the foregoing amendments, Claims 49 and 79-83, directed to pharmaceutical compositions, have been canceled without prejudice or disclaimer.

Finally by the foregoing amendments, Claims 74 and 76-78 have been amended to correct a minor and typographical error regarding the article preceding the monoclonal antibody or fragment aspect of the claimed kits. No new matter has been added.

Request for Clarification

Prior to addressing the merits of the outstanding Official Action, Applicants respectfully request clarification regarding Claims 43, 45, 47 (which depends from Claim 45), 52 (which depends from Claim 47), 64, 66, 74, and 76.

Specifically, the Advisory Action mailed September 2, 2003 (Paper No. 29) stated that Claims 40-41, 43, 45, 47-48, 50-52, 54-57, 64, 66, 74 and 76 "would be allowable if submitted separately." *See Advisory Action mailed September 2, 2003, Page 2 and Page 1, Item 4.* Not one word of these claims was changed in the Amendment filed September 11, 2003.

In light of the foregoing, Applicants respectfully request renewed allowance of these claims or an explanation as to their change in status.

Rejections Under 35 U.S.C. § 112, First Paragraph – Written Description

Claims 45-47, 52, and 64-73 were rejected under 35 U.S.C. § 112, First Paragraph, as purportedly failing to comply with the written description requirement. *See Official Action mailed November 25, 2003, Pages 2-4, ¶ 3.* This rejection is respectfully traversed.

As addressed above, Applicants seek clarification regarding Claims 45, 47, 52, 64, and 66. With respect to remaining rejected Claims 46, 65, and 67-73, not to acquiesce to the Examiner's rejection, but solely to facilitate prosecution, Applicants have amended these claims to specify that "any antigen/antibody type reaction produce formed" is detected.

Because the Examiner agrees that "the specification does provide support for the phrase 'detection of any antigen-antibody the reaction product formed' (See *Official Action mailed November 25, 2003, Page 3*), Applicants believe the rejection has been rendered moot. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, First Paragraph, rejection of Claims 45-47, 52, and 64-73.

Rejection of Claim 43 Under 35 U.S.C § 112, First Paragraph – Written Description

Claim 43 was rejected under 35 U.S.C. § 112, First Paragraph, as allegedly failing to comply with the written description requirement. See *Official Action mailed November 25, 2003, Page 4, ¶ 4*.

As indicated above, because Claim 43 was allowable as of the Advisory Action mailed September 2, 2003 (Paper No. 29) and because the language of Claim 43 has not changed since that time, Applicants believe this rejection issued in error. Accordingly, Applicants respectfully request allowance of Claim 43 or clarification as to its change in status.

Rejection Under 35 U.S.C. § 112, First Paragraph – Enablement

Claims 49 and 79-83 were rejected under 35 U.S.C. § 112, First Paragraph, as purportedly not enabled. See *Official Action mailed November 25, 2003, Pages 4-6, ¶ 5*. This rejection is respectfully traversed.

Not to acquiesce in the Examiner's rejection, but solely to facilitate prosecution, Applicants, by foregoing amendments, have cancelled Claims 49 and

79-83 without prejudice or disclaimer to filing one or more continuing applications on the subject matter thereof. As a result, Applicants believe that foregoing rejection has been rendered moot and respectfully request withdrawal thereof.

Rejections Under 35 U.S.C. § 112, Second Paragraph – Indefiniteness

Claims 45, 46, 52, 64-73, 74, and 76-78 were rejected under 35 U.S.C. § 112, Second Paragraph, as purportedly being indefinite. See *Official Action mailed November 25, 2003, Pages 6-9, ¶¶ 6*. This rejection is respectfully traversed.

As indicated above, Claims 45, 52, 64, 66, 74, and 76 were indicated as allowable in the Advisory Action mailed September 2, 2003. Applicants respectfully request renewed allowance of these claims or an explanation as to their change in status.

With respect to remaining Claims 46, 65, and 67-73, the Examiner has characterized these claims as incomplete methods for detecting any product. See *Official Action mailed November 25, 2003, Page 7*. By the foregoing amendments, these claims have been amended to specify that "any antigen/antibody type reaction product formed" is detected. Applicants believe these amendments have rendered moot the foregoing rejection, and respectfully request withdrawal thereof.

With respect to Claims 64-69, the Examiner believes that these claims were incomplete methods for detecting any product, albeit specific or non-specific. See *Official Action mailed November 25, 2003, Page 7, ¶¶ 1-2*. By the foregoing amendments, Claims 64-69 have been amended to specify that the claimed methods detect any "antigen/antibody type reaction product formed." Applicants believe this

has rendered moot the Examiner's concern regarding detecting *any* product. However, should the Examiner disagree, to expedite prosecution Applicants respectfully request that the Examiner phone the undersigned attorney with suggestions as to claim language for consideration by the Applicants.

With respect to Claims 74 and 76-78, these claims have been amended to correct a minor and typographical error regarding the article preceding the monoclonal antibody or fragment aspect of the claimed kits. As amended, these claims mirror the language of allowed Claim 75, which specifies that the kits contain "a monoclonal antibody or fragment" according to the referenced claim. Applicants believe this has rendered moot the Examiner's concern regarding which antibody is contained within the kit. *See Official Action mailed November 25, 2003, Pages 8-9.*

In light of the foregoing, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, Second Paragraph, indefiniteness rejection of Claims 45, 46, 52, 64-73, 74, and 76-78.

Rejections Under 35 U.S.C. § 102(b) Over Akuzawa

Claims 64, 66-69, and 71-73 were rejected under 35 U.S.C. § 102(b) as purportedly anticipated by the abstract of Akuzawa *et al.*, "Manufacture Of Monoclonal Antibodies For External Cell Membrane of *Tayorella equigenitalis*" ("Azukawa") *See Official Action mailed November 25, 2003, Page 9, ¶ 7.* This rejection is respectfully traversed.

As indicated above, Claims 64 and 66 were characterized as allowable in the Advisory Action mailed September 11, 2003. With respect to remaining Claims 67-69 and 71-73, Applicants respectfully reiterate that anticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of the claimed invention. See *Electro. Med. Sys., S.A. v. Cooper Life Sciences*, 34 F.3d 1048, 1052 (Fed. Cir. 1994). Moreover, inherency may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. See *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (quoting *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981)).

As amended, Claims 67-69 and 71-73 require identifying a bacterium of the *T. equigenitalis* species by bringing the specimen or culture to be analyzed into contact with an effective quantity of the monoclonal antibodies that recognize a 120, 150, 52.7, or 22 kDa *T. equigenitalis* protein or fragments thereof and then detecting the antigen/antibody type reaction product formed that is indicative of the bacterium. The Examiner asserts that "[i]nherently the reference anticipates the instantly claimed methods that utilize any monoclonal antibody effective to form a reaction complex between a *Taylorella equigenitalis* antigen and the monoclonal antibody." See *Official Action mailed November 25, 2003, Page 9*. Applicants respectfully stress that the claimed methods do not simply utilize "any monoclonal antibody." Moreover, Akuzawa does not establish that the disclosed monoclonal antibodies will recognize a 120, 150, 52.7, or 22 kDa *T. equigenitalis* protein or fragment thereof, as required by the rejected claims. As stated above, the mere fact that a certain thing

may result from a given set of circumstances is not sufficient to maintain an anticipation rejection.

In light of the foregoing, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(b) rejection of Claims 64, 66-69, and 71-73 over Akuzawa.

CONCLUSION

From the foregoing, further and favorable consideration in the form of a Notice of Allowance is respectfully requested and earnestly solicited.

In the event that there are any questions relating to this response, or the application in general, it would be greatly appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,
BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By:


Elin M. Dunston
Registration No. 51,147

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Date: March 25, 2004